

REMARKS

Claim 21 has been amended for clarification to correlate with dependent claim. Claim 59-61 has been added to define the invention in alternative language. Support for this amendment is found in the original specification on page 10, penultimate paragraph.

Claims 21-58 are currently pending in the present application and have been rejected by the Examiner under 35 USC 103(a) as being unpatentable over W0 97/25606 to Rasmussen in view of U.S. 6,164,144 to Berg and U.S. 5,615,671 to Schoonen.

In this rejection, the Examiner states that Rasmussen, et al. teaches a device and method for liquid-liquid micro extraction with the method comprising providing a carrier, modifying the carrier, immobilizing a solvent (acceptor solution) on the carrier surface, contacting the carrier with the sample, concentrating and fixing the analyte of interest to the solvent and analyzing the carrier (emphasis added).

The Examiner further relies on Berg for teaching a method and device for solid-state micro extraction which teaches the use of a hollow fiber which acts as a “sponge”.

The Examiner confirms an earlier acknowledgement that neither Rasmussen or Berg teach permeability of a hollow fiber to analyte.

The Examiner then reaches to Schoonen, et al. for teaching a process and device for monitoring analyte levels, wherein a tissue is provided with a hollow fiber having a pore size between the size of the analyte and the size of the macro molecules. A second hollow fiber is provided that is permeable for analyte but not for the macro molecules.

The Examiner concludes it would have been prima facie obvious to one skilled in the art at the time the invention was made to use a hollow fiber permeable to analyte and an acidified acceptor solution as taught by Berg and Schoonen, et al. with the invention of Rasmussen, et al.

The Examiner also stated “by using a hollow fiber, one would have been able to fill the fiber with acceptor solution rather than immobilizing the solution on the surface of the fiber.”

The Applicants submit that this opinion by the Examiner, namely “one would have been able to fill the fiber...”, is unsupported.

It has been established that unsupported opinions of the Examiner do not provide the factual basis required by the Supreme Court in the Deere case (148 USPQ 459, 1966) for the determination of obviousness under Section 103 (In re Wagner and Folkers, 152 USPQ 552 (CCPA 1967)). Wagner and Folkers states that neither can such (Examiner) opinions establish a “presumption” of obviousness, and that subjective opinions are of little weight against contrary evidence.

The Examiner has provided no factual support for this conclusion and a determination of obviousness must be based on facts not on unsupported generalities. In re Freed, 165 USPQ 570 (CCPA 1970).

In any event, the Examiner’s statement as to “using a hollow fiber, one would have been able to fill the fiber...” is clearly a conclusion based upon the Examiner’s personal opinion and one which is not supported by any stated factual basis. As enunciated by the CCPA in In re Warner and Warner, 154 USPQ 173, 178 (CCPA 1973):

“A rejection based on Section 103 clearly must rest on a factual basis, and these facts must be interpreted without hindsight reconstruction of the invention from prior art...the patent office has the initial duty as supplying the factual basis for its rejection. It may not, because they doubt that the invention is patentable, resort to speculation, unfounded assumptions, or hindsight to supply deficiencies in its factual basis.”

Accordingly, without factual support, the Applicants submit that the Examiner has in fact not made a prima facie case of obviousness for the rejection of claims 21-58 under 35 USC 103(a) on the basis of the Rasmussen, Berg and Schoonen, et al. references. Without further factual support, the Examiner's opinion is unfounded and accordingly a prima facie case of obviousness has not been made.

In addition, independent claims 21, 31, 42, 48, and 54 include structure and method utilizing a first and a second hollow container in which the second container is disposed within the first container and includes a membrane wall with the fibers permeable to the analyte.

The Applicants submit there is no teaching whatsoever in Rasmussen, Berg, or Schoonen for transport of the analyte from the sample solution through a membrane wall and into the acceptor solution.

While the Schoonen, et al. reference utilizes hollowed fibers, they are in fact serially connected, as clearly shown in Figure 2 as indicated by the probe 7 and enzyme reactor 8. Accordingly, even if assuming, arguendo, the Examiner's opinion that one would have been able to fill the fiber with acceptor solution, there is simply no suggestion, teaching, or hint whatsoever of utilizing a second hollow container which is disposed in a first container.

The apparatus and method claims of the present application define the invention as including transport of analyte through a membrane wall of a second hollow container disposed within the solution comprising a dissolved analyte. Further, method claims 38-51 define a process for allowing analyte equilibrium to be established between the sample solution and an acceptor solution through a membrane wall. No such method including allowing analyte equilibrium is suggested, taught, or inferred by any other references cited by the Examiner.

As early argued by the Applicants, and hereinabove noted, each of the Rasmussen and Berg references relate to structure and methods for the separation of an analyte using a surface phenomenon. Rasmussen, for example, provides for a method for immobilization of a solvent on the

surface of a carrier and contacting the surface modified carrier with a material through concentrate and fix the substance to be analyzed on the surface and thereafter desorbing the concentrated substance from the carrier surface.

Berg also teaches a surface phenomenon. Although Berg discloses a needle 24, it includes a stationary phase 32 which covers an inner surface of a needle. Absorption and desorption of materials from a stationary phase 32 is taught.

Contrary to these disclosures, the present invention is directed to an apparatus device for carry out liquid-liquid micro extraction or liquid-liquid-liquid micro extraction utilizing a membrane wall to permeate an analyte in which the analyte of interest passes through the membrane wall and is collected on an opposite of the membrane wall than the side exposed to the sample solution with dissolved analyte.

Newly cited Schoonen, et al. teaches the perfusion of a hollow fiber with a macro molecule-free perfusion fluid compatible to tissue so that the analyte enters the perfusion fluid through the hollow fiber. Thereafter, the perfusion fluid with analyte is fed through the hollow fiber to a reactor.

This is totally contrary to the surface phenomenon used by Rasmussen and Berg hereinabove discussed.

Thus, the combination proposed by the Examiner is improper since references cannot be properly combined if the effect would destroy the invention on which one of the reference patents is based. Ex parte Hartmann, 186 USPQ 366 (PT TM Board of Appeals 1974).

In the case at hand, the Schoonen, et al. reference is based upon the perfusion of a hollow fiber which is in contrast with the surface adsorption and desorption phenomenon essential for the Rasmussen and Berg apparatus and procedures. This and of itself provides a contrary reason for combining the references.

The Applicants submit that there must be some logical reason apparent from positive, concrete evidence of record that justifies the combination of primary and secondary references. In re Regel, Bechel, and Plempel, 188 USPQ 136, 139 (CCPA 1975); Berghauser, et al. v. Dann, 204 USPQ 393, 396 (Dist. Ct. Dist. of Columbia, 1978); ACH Hospital Systems, Inc. v. Montefiore Hospital, et al., 221 USPQ 929, 933 (CAFC 1994); and In re Imperato, 179 USPQ 730, 732 (CCPA 1973).

The patent office bears the initial burden of presenting a prima facie case of patentability. In re Glaug, 62 USPQ 2d 1151, 1152 (Fed. Cir. 2002); In re Oetiker, 24 USPQ 2d 1443, 1444 (Fed. Cir. 1992); In re Piasecki, 223 USPQ 785, 788 (Fed. Cir. 1994).

As hereinabove noted, there is no motivation to combine the references if the combination teaches away from the combination.

A reference may be said to teach away when a person of ordinary skill, upon reading of the reference would be discouraged from following the path set out in the reference. Such a person would be led in a direction divergent from the path that was taken by Applicant. Tech Air, 52 USPQ 2d, 1294, 1298 (Tech Air, Inc. v. Denso Manufacturing, Michigan, Inc. (US Court of Appeals Federal Circuit, 1999) citing In re Gurley, 31 USPQ 2d, 1130, 1132 (U.S. Court of Appeals, 1994)). In the case at hand, the Rasmussen and Berg references rely on a surface phenomenon of absorption and desorption and such phenomenon is not consistent with the profusion of a fiber as taught by Schoonen, et al. Thus, there is no motivation when a proposed modification renders the reference inoperable for its intended purpose. McGinley v. Franklin Sports, Inc., 60 USPQ 2d 1001, 1010 (U.S. Court of Appeals Federal Circuit 2001).

In addition, the Examiner's opinion, as hereinabove noted, is in the nature of a "obvious to try" which is not the standard for obviousness. Rejections couched as obviousness rejections are improper because they merely reflect an opinion that would have been obvious to try a combination of modification. "Obvious to try" is not the standard under Section 103 for obviousness or motivation for combination or modification. In re O'Farrell, 7 USPQ 2d 1673, 1681 (Fed. Cir.

1988).

Further, assuming *arguendo*, that the reference may be modified or combined does not make the modification or combination obvious unless the prior art suggest the desirability of the modification or combination. In re Fritch, 23 USPQ 2d 1780, 1783 (Fed. Cir. 1992).

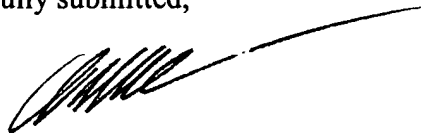
As hereinabove noted, the differences in the basic operational principles between Rasmussen and Berg and Schoonen, et al. references cannot provide any suggestion for the desirability of the combination or modification speculated by the Examiner.

Accordingly, in view of the arguments hereinabove set forth, the Applicants submit that the Examiner has not made a *prima facie* case of obviousness for the rejection of claims 21-58 under 35 USC 103(a) on the basis of the Rasmussen, Berg, and Schoonen, et al. references.

In view of the arguments hereinabove set forth, it is submitted that each of the claims now in the application define patentable subject matter not anticipated by the art of record and not obvious to one skilled in this field who is aware of the references of record. Reconsideration and allowance are respectively requested.

A check in the amount of \$71 is enclosed for the added claims fees. Please charge any additional fees or credit any overpayment to account no. 08-0114.

Respectfully submitted,



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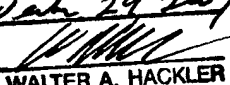
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